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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,385	02/05/2002	John E. Adamou	469290-589	8182

7590 02/23/2005

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/067,385

Applicant(s)

ADAMOU ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,11-13,18,21 and 23 ~~is/are~~ pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 ~~is/are~~ allowed.
- 6) ☒ Claim(s) 1,3,11,18,21 and 23 ~~is/are~~ rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Sequence alignment report (1)</u> . |

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 10/20/04 in response to the non-final Office Action mailed 02/27/04. With this, Applicants have amended the specification.

Status of Claims

- 2) Claims 2, 5-10, 14-17, 19, 20 and 22 have been canceled via the amendment filed 10/20/04.

Claims 1, 3, 4, 11, 18 and 21 have been amended via the amendment filed 07/26/04.

New claim 23 has been added via the amendment filed 07/26/04.

Claims 1, 3, 4, 11-13, 18, 21 and 23 are pending.

Claims 1, 3, 4, 11, 18, 21 and 23 are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

- 5) The objection to the specification made in paragraph 6(a) of the Office Action mailed 02/27/04 is withdrawn in light of Applicants' amendment to the specification.
- 6) The objection to the specification made in paragraph 6(b) of the Office Action mailed 02/27/04 is withdrawn in light of Applicants' amendment to the specification.

Rejection(s) Moot

- 7) The rejection of claim 2 made in paragraph 8 of the Office Action mailed 02/27/04 under 35 U.S.C § 101 as being directed to a non-statutory subject matter, is moot in light of Applicants' cancellation of the claim.
- 8) The rejection of claim 2 made in paragraph 9 of the Office Action mailed 02/27/04 under 35 U.S.C. § 112, first paragraph, as containing inadequate written description, is moot in light of

Applicants' cancellation of the claim.

9) The rejection of claims 2 and 22 made in paragraph 10 of the Office Action mailed 02/27/04 under 35 U.S.C. § 112, first paragraph, as being non-enabled with regard to the scope, is moot in light of Applicants' cancellation of the claims.

10) The rejection of claim 22 made in paragraph 13(e) of the Office Action mailed 02/27/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

11) The rejection of claim 22 made in paragraph 13(h) of the Office Action mailed 02/27/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

12) The rejection of claim 2 made in paragraph 13(i) of the Office Action mailed 02/27/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

13) The rejection of claim 22 made in paragraph 15 of the Office Action mailed 02/27/04 under 35 U.S.C. § 102(b) as being anticipated by Choi *et al.* (WO 98/18930 A2 – Applicants' IDS) ('930), is moot in light of Applicants' cancellation of the claim.

Rejection(s) Withdrawn

14) The rejection of claims 1, 3, 4, 18 and claims dependent therefrom made in paragraph 8 of the Office Action mailed 02/27/04 under 35 U.S.C. § 101 as being directed to a non-statutory subject matter, is withdrawn in light of Applicants' amendment to the claims.

15) The rejection of claims 1, 3 and 11 made in paragraph 9 of the Office Action mailed 02/27/04 under 35 U.S.C. § 112, first paragraph, as containing inadequate written description, is withdrawn in light of Applicants' amendment to the claims and/or the base claim.

16) The rejection of claim 11 made in paragraph 13(a) of the Office Action mailed 02/07/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

17) The rejection of claim 1 made in paragraph 13(b) of the Office Action mailed 02/27/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

18) The rejection of claim 18 made in paragraph 13(c) of the Office Action mailed 02/27/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

19) The rejection of claim 11 made in paragraph 13(d) of the Office Action mailed 02/27/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

20) The rejection of claim 21 made in paragraph 13(f) of the Office Action mailed 02/27/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn.

21) The rejection of claim 11 made in paragraph 13(g) of the Office Action mailed 02/27/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

22) The rejection of claim 21 made in paragraph 13(h) of the Office Action mailed 02/27/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

23) The rejection of claims 3, 4, 11, 21 and 22 made in paragraph 13(i) of the Office Action mailed 02/27/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

24) The rejection of claim 21 made in paragraph 15 of the Office Action mailed 02/27/04 under 35 U.S.C. § 102(b) as being anticipated by Choi *et al.* (WO 98/18930 A2 – Applicants' IDS) ('930), withdrawn in light of Applicants' amendment to the claim.

Rejection(s) Maintained

25) The rejection of claims 1, 3, 4, 11 and 21 made in paragraph 10 of the Office Action mailed 02/27/04 under 35 U.S.C. § 112, first paragraph, as being non-enabled with regard to the scope, is maintained for reasons set forth therein and herebelow.

Applicants cite case law and contend that the test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure coupled with information known in the art without undue experimentation. Applicants submit that the experiments to test whether a variant binds to an antibody that binds *Streptococcus pneumoniae* are not undue, and are routine in the art. Applicants state that Examples 1 and 2 in the

specification disclose ELISA methods that could be used to determine if SEQ ID NO: 8 variants bind an antibody that binds to *Streptococcus pneumoniae*. Applicants cite *In re Angstadt*, 537 F.2d 498, 504 (CCPA, 1976) and state that the test of enablement is not whether any experimentation is necessary, but whether it is undue, if experimentation is necessary. Applicants submit similar arguments with regard to the vaccine claimed in claims 11 and 21. With regard to the lack of evidence in the specification raised by the Office establishing that polypeptide variants of SEQ ID NO: 8 bind to an antibody that binds to *Streptococcus pneumoniae* and serve as a vaccine, Applicants cite MPEP 2164.04 and state that the Office has the initial burden of establishing a reasonable basis to question enablement of the claimed invention. Applicants cite case law and state that the mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it. Applicants state that having no 'evidence' is not sufficient to establish a 35 U.S.C. § 112 rejection and that the burden lies with the Office to show why SEQ ID NO: 8 variants would not elicit an antibody response against *Streptococcus pneumoniae*. Applicants further submit that:

(a) It has been well known for over a decade which amino acids can and cannot be substituted without causing certain effects on the antigenicity of a protein;

(b) The mere fact that the Office has found a few journal articles showing that the one substitution causes detrimental affect to a protein does not constitute evidence that the whole field is unpredictable.

(c) The focus on the instant claims should be on whether the antigenicity of the variant proteins has changed and whether this can be tested using routine methods. Determining antigenicity of a protein or polypeptide using an algorithm or a computer program, such as, DNASTAR that predicts antigenic determinants has been known to persons skilled in the art for a long time and therefore the art is not unpredictable.

(d) Any variant could be easily tested using the methods disclosed in example one and two of the specification rendering such predictability unnecessary. At the time of the application was filed, all the methods needed to practice the invention were well known. These experiments are routine and are not considered undue experimentation.

Applicants' arguments have been carefully considered, but are not persuasive for the following reasons. The Office has clearly met the burden of showing why SEQ ID NO: 8 variants would not elicit an antibody response against *Streptococcus pneumoniae*. See paragraph 10 of the Office Action mailed 02/27/04. Claims 1, 2 and 11, as amended, encompass a composition comprising an isolated polypeptide variant having at least 80% or 95% identity to the amino acid sequence of SEQ ID NO: 8 which variant is *required* to elicit an antibody 'specific' for *Streptococcus pneumoniae*, or antibodies 'protective' against *Streptococcus pneumoniae* on administration to a mammal. This means that the polypeptide variant having as much as 20% or 5% non-identity with the amino acid sequence of SEQ ID NO: 8 is required to be 'immunogenic' and is required to induce an antibody that is specific for *Streptococcus pneumoniae* and/or protective against *Streptococcus pneumoniae* on administration to a mammal. As established in paragraph 10 of the Office Action mailed 02/27/04, the art reflects that a substitution of one or more amino acid residues results in a polypeptide variant that is biologically or antigenically different from the native polypeptide. Houghten's teaching establishes that although such variant may produce antibodies, the resultant antibodies may not recognize the native polypeptide antigen, i.e., SEQ ID NO: 8 in this case. Antibodies that do not specifically recognize the native polypeptide cannot be expected to be 'protective against *Streptococcus pneumoniae*' since protection is immunospecific to an antigen. The polynucleotide homologs or variants isolated based on percent homology do not predictably display the functions of the native molecules absent an independent showing that the variant sequence produces a polypeptide that functions as recited. In other words, the biological functions of a gene product based solely on percent sequence identity is unreliable and unpredictable absent a supportive showing by production of a polypeptide variant having the required functions. There is lack of showing that the claimed polypeptide variant remains *Streptococcus pneumoniae*-specific and confers protection against *Streptococcus pneumoniae*. Thus, contrary to Applicants' assertion, the Office has met the burden of establishing a reasonable basis for the lack of enablement. Using several publications, the Office has established the art-recognized unpredictability factor associated with the structure-function relationship of a varied protein or polypeptide. It is noted that Applicants have advanced no

specific arguments with regard to the disclosure of the Office's citations of Bowie *et al.*, Burgess *et al.*, Lazar *et al.* and Houghten *et al.* Predictability or unpredictability in the art is one of the *Wands* factors for enablement. Because of the unpredictability documented in the art, one of skill in the art would look into Applicants' specification for specific teaching and guidance as to how to make a polypeptide variant as recited that has the capacity to elicit *Pneumococcus*-specific antibodies such that the composition comprising the variant serves as a vaccine and 'protects' against *Streptococcus pneumoniae*. This specific teaching and guidance is lacking in the instant specification. The enablement or a concrete showing in the instant case is limited to the polypeptide having the amino acid sequence of SEQ ID NO: 8. Furthermore, while producing the claimed polypeptide variants, if one nucleotide base is deleted or inserted at a single position within the coding sequence, all the codons downstream of that deletion or insertion will be frame-shifted. If such a frame-shift takes place near the 5' end of the gene, it is highly unlikely that the expressed polypeptide variant will have any thing in common structure-wise or function-wise with the *Streptococcus pneumoniae*-specific protective polypeptide having the amino acid sequence of SEQ ID NO: 8. Due to the lack of specific guidance and disclosure as to the precise structure of the polypeptide variants as recited, which variants are functional in that they are specific for and protective against *Streptococcus pneumoniae*; the lack of demonstration of their antigenic, immunogenic, and/or protective ability; the lack of working examples enabling the full scope of the claims; the art-recognized unpredictability factor associated with the functions of a polypeptide following variation or deletion; the breadth of the claims; and the quantity of experimentation necessary, undue experimentation would have been required to practice the invention as claimed. With the establishment in the art that a single amino acid substitution can drastically alter the biological property of a polypeptide, it is reasonable to conclude that the claimed polypeptide variant, having as much as 20% or 5% dissimilarity, would not elicit antibodies that are 'specific to *Streptococcus pneumonaie*' and 'protective against *Streptococcus pneumonaie*', absent evidence to the contrary. Although one may produce polypeptide variants as recited using algorithms or computer programs available in the art, the ability of the resultant polypeptide variants to elicit an antibody 'specific' for and 'protective' against *Streptococcus pneumonaie* on administration to a mammal is not predictable,

absent a concrete showing. The rejection stands.

26) The rejection of claim 11 made in paragraph 11 of the Office Action mailed 02/27/04 under 35 U.S.C. § 112, first paragraph, as being non-enabled with regard to the scope, is maintained for reasons set forth therein and herebelow.

Applicants assert that claim 11 has been amended to replace the broad limitation 'animal' with --mammal-- and the limitation 'an organism of the genus *Streptococcus*' with --*Streptococcus pneumoniae*--.

Applicants' amendments to the claim have been noted. With regard to the dependency of claim 11 from claim 4, there is no lack of enablement. However, with regard to the dependency of claim 11 from claim 1, 3 and 23, the rejection stands. An immunogenic 'fragment' of the amino acid sequence of SEQ ID NO: 8 that has the capacity to elicit 'protective antibodies in a mammal against *Streptococcus pneumonia*' is not identified in the instant case. Absent a showing, the 'protective' capacity of a given polypeptide is not predictable. The rejection stands.

New Rejection(s)

Applicants are asked to note the following new and/or modified rejection(s) in this Office. The new rejections are necessitated by Applicants' amendments to the claims and/or submission of new claim(s).

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

27) Claims 1, 3 and 11 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1, as amended, includes the new limitations: an isolated polypeptide having an amino acid sequence with at least '80%' identity to the amino acid sequence of SEQ ID NO: 8 wherein said polypeptide 'when administered to a mammal elicits an antibody specific for *Streptococcus pneumoniae*'. The dependent claim 3, as amended, includes the new limitation: wherein 'the percent identity to the amino acid sequence of SEQ I NO: 8' is at least 95%. Applicants point to lines 10-24 on page 11 and line 14 on page 12 through line 30 of page 13 as providing the descriptive support for the added limitations. However, there is no descriptive

support in these parts of the specification, as originally filed, for an immunogenic composition comprising an isolated polypeptide having an amino acid sequence with 'at least 80%' or 'at least 95%' identity to the amino acid sequence of SEQ ID NO: 8 wherein the polypeptide 'when administered to a mammal elicits an antibody specific for *Streptococcus pneumoniae*', irrespective of whether or not said *Streptococcus pneumoniae* comprises or produces the polypeptide of SEQ ID NO: 8. An isolated polypeptide having 'at least 80%' or 'at least 95%' identity to the amino acid sequence of SEQ ID NO: 8 and concurrently having the ability to elicit an antibody 'specific to *Streptococcus pneumoniae*', or the ability to 'elicit protective antibodies in a mammal against to *S. pneumoniae*' lacks descriptive support in the specification, as originally filed. Therefore, the above-identified limitations in the claim(s) are considered to be new matter. New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). See M.P.E.P. 608.04 to 608.04(c).

Applicants are invited to point to the descriptive support in specific part(s) of the disclosure, as originally filed, for the limitations identified above, or to remove the new matter from the claims and/or the base claim(s).

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

28) Claims 18 and 21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 18, as amended, is vague, indefinite and confusing in the recitation: 'isolated polypeptide or immunogenic fragments thereof having the amino acid sequence of SEQ ID NO: 8', because it is unclear whether or not the amino acid sequence of SEQ ID NO: 8 represents the isolated polypeptide. Do the recited 'immunogenic fragments' of the isolated polypeptide comprise the amino acid sequence of SEQ ID NO: 8?

(b) Claim 21 has improper antecedent basis in the limitation 'said immunogenic fragment'. Claim 21 depends from claim 18, which includes the recitation 'immunogenic fragments', but not an 'immunogenic fragment'.

(c) Claim 21, which depends from claim 18, is also rejected as being indefinite, because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C § 102

29) Claims 11, 18 and 23 are rejected under 35 U.S.C § 102(b) as being anticipated by Choi *et al.* (WO 98/18930 A2 – already of record) ('930) as evidenced by Harlow *et al.* (*In: Antibodies: A Laboratory Manual*. Cold Spring Harbor Laboratory, Chapter 5, p. 76, 1988).

Choi *et al.* ('930) disclosed a polypeptide from *Streptococcus pneumoniae* which includes the fragments comprising amino acid residues 657-773 of the instantly recited SEQ ID NO: 8, and a vaccine comprising the same and a pharmaceutically acceptable carrier for inducing protective antibodies against *Streptococcus pneumoniae*. See the sequence search report attached herein and to the Office Action mailed 02/27/04; and pages 4 and 62, SEQ ID NO. 68 in Table 1 of Choi *et al.* That an amino acid sequence comprising 657-773 residues intrinsically comprises one or more six amino acid-long fragments that are long enough to be immunogenic is inherent from the teachings of Choi *et al.* in light of what is known in the art. For instance, the art recognizes that the smallest peptides which elicit antibodies that bind to the original full length protein are 6 amino acids in length. See the first sentence under 'Size of the Peptide' on page 76 of Harlow *et al.*

Claims 11, 18 and 23 are anticipated by Choi *et al.* ('930). Harlow *et al.* is **not** used as a secondary reference in combination with Choi *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Choi *et al.* with the unrecited limitation(s) being inherent in view of what is known in the art as explained above. See *In re Samour* 197 USPQ 1 (CCPA 1978).

Remarks

30) Claims 1, 3, 11, 18, 21 and 23 stand rejected. Claim 4 is allowable.

31) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

32) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The central Fax number for submission of amendments or responses is (571) 273-8300.

33) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

34) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

February, 2005


S. DEVI, PH.D.
PRIMARY EXAMINER

RESULT 9
 AAW55096
 ID AAW55096 standard; protein; 117 AA.
 XX
 AC AAW55096;
 XX
 DT 02-OCT-1998 (first entry)
 XX
 DE Streptococcus pneumoniae SP0043 protein.
 XX
 KW Streptococcus pneumoniae; antigen; vaccine; infection; diagnosis;
 KW detection; pneumonia; otitis media; meningitis.
 XX
 OS Streptococcus pneumoniae.
 XX
 PN WO9818930-A2.
 XX
 PD 07-MAY-1998.
 XX
 PF 30-OCT-1997; 97WO-US019422.
 XX
 PR 31-OCT-1996; 96US-0029960P.
 XX
 PA (HUMA-) HUMAN GENOME SCI INC.
 XX
 PI Kunsch CA, Choi GH, Johnson LS, Hromockyj A;
 XX
 DR WPI; 1998-272224/24.
 DR N-PSDB; AAV27357.
 XX
 PT Nucleic acid encoding antigenic peptide(s) from Streptococcus pneumoniae
 PT - or their epitope-containing fragments, useful in protective or
 PT therapeutic vaccines, and for diagnosis.
 XX
 PS Claim 11; Page 62; 118pp; English.
 XX
 CC The present sequence represents a protein from Streptococcus pneumoniae.
 CC The nucleic acid sequence encoding the Streptococcus pneumoniae protein
 CC can be useful in vaccines for inducing protective antibodies against
 CC Streptococcus pneumoniae, for treatment or prevention of infection e.g.
 CC pneumonia, otitis media or meningitis. Probes based on the nucleic acid
 CC are used to detect Streptococcus infection (by usual hybridisation or
 CC amplification methods), also for isolating Streptococcus genes or their
 CC allelic variants. The protein can be used similarly to detect specific
 CC antibodies in standard immunoassays, especially for diagnosing or
 CC monitoring infections. Antibodies which bind the protein are used to
 CC detect corresponding antigens, to purify the protein and for passive
 CC immunisation (optionally coupled to a toxin). Vaccines are administered,
 CC e.g. by injection, orally or through the skin, typically at 0.01-1000
 CC (especially 10-300) mu g/ml per dose
 XX
 SQ Sequence 117 AA;

Query Match 15.3%; Score 615; DB 2; Length 117;
 Best Local Similarity 100.0%; Pred. No. 3.2e-28;
 Matches 117; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 657 YKGELEKGYQFDGWEISGFEGKKDAGYVINLSKDTPIKPVFKKIEEKKEENKPTFDVSK 716
 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
 Db 1 YKGELEKGYQFDGWEISGFEGKKDAGYVINLSKDTPIKPVFKKIEEKKEENKPTFDVSK 60
 Qy 717 KKDNPQVNHSQLNESHKEDLQREEHSQKSDSTKDVATVLDKNNISSKSTTNNPNK 773
 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
 Db 61 KKDNPQVNHSQLNESHKEDLQREEHSQKSDSTKDVATVLDKNNISSKSTTNNPNK 117

SEQ ID NO. 8